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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,427	12/17/2003	Joel Morganroth	D5859-00021	8208
8933	7590	06/06/2008		
DUANE MORRIS, LLP IP DEPARTMENT 30 SOUTH 17TH STREET PHILADELPHIA, PA 19103-4196			EXAMINER  LAYNO, CARL HERNANDZ	
			ART UNIT	PAPER NUMBER
			3766	
			MAIL DATE	DELIVERY MODE
			06/06/2008 PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/738,427

**Applicant(s)**

MORGANROTH, JOEL

**Examiner**

Carl H. Layno

**Art Unit**

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 10-18 and 20-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-8, 10, 16-18, 45 and 46 is/are allowed.
- 6) ☐ Claim(s) 1-5, 11-15, 20-42 and 47-54 is/are rejected.
- 7) ☒ Claim(s) 43 and 44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/10/07, 8/21/07
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Acknowledgement is made of applicant's amendment, which was received by the Office on 7/2/2007.
2. Claims 9 and 19 are cancelled, while claims 1-9, 10-18 and 20-54 are pending.

#### ***Information Disclosure Statement***

3. The information disclosure statements (IDS) submitted on 7/10/2007 and 8/21/2007 were filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

#### ***Claim Objections***

4. After considering the applicant's arguments, the claim objections to claims 49 and 53 have been withdrawn.

#### ***Claim Rejections - 35 USC § 112***

5. Applicant's amendments to claims 6 and 16 are acknowledged and accepted. As a result, the 35 USC 112(2) rejection of claims 6 and 16 have been withdrawn.
6. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 31 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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8. Claims 31 and 42 recite the limitation "said clinical study" in the last line of each claim. There is insufficient antecedent basis for this limitation in the claims.

***Response to Arguments***

9. Applicant's arguments with respect to claims 1-8, 10-18 and 20-54 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-5 and 11-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Rabin (US 6,603,464).

12. Regarding claims 1 and 11, Rabin discloses a computer implemented method and system for data collection and verification. Rabin discloses receiving digital parameter data, said digital parameter data including demographic data and ECGs (Col. 6, lines 41-47). Rabin discloses that the data is collected for clinical study organizers (Col. 8, lines 36-40). Rabin further discloses that when a problem is identified with collected demographic information, a query is automatically sent to staff in order to elicit resolution of the problem (Col. 8, lines 48-67).

13. Regarding claims 2-4 and 12-14, Rabin discloses that the automatic query can be resolved internally (i.e., an auditory alert to an internal contact) or externally (i.e., phone external contacts).

14. Regarding claims 5 and 15, a potential drug interaction would violate rules associated with studies, and furthermore constitutes missing data from the demographic data.

15. Claims 20-42 and 47-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Badilini (US 2002/0172404).

16. Regarding claims 21, 22, 31-33 and 42, Badilini discloses an ECG processing system and method wherein ECG data is received by scanning an ECG plot 10 with scanner 64, or directly from an ECG machine, wherein an ECG plot is inherently produced from at least one ECG lead and contains a plurality of a patient's heartbeats (par. 0038, 0062 and figure 4). An ECG tracing image with a plurality of heartbeats is then displayed on a display of a user terminal (par. 0038). The user then identifies a plurality of interval points for a plurality of intervals on the displayed ECG tracing image to be measured using a moveable caliper (i.e., mouse pointer) (par. 0046-0058). As seen in figure 9, a plurality of time durations of the identified intervals are determined, recorded and displayed to a party. Furthermore, an annotated ECG tracing image showing the markings made by the user is saved (par. 0060).

17. Regarding claim 20, the scanner is a means for receiving a plurality of ECGs from a plurality of patients. Furthermore, the computer controlled method described above is a means for receiving interval duration data from a plurality of heartbeats, and all computers have means for connecting to a computer network (i.e., a modem, ethernet cables or USB cables).

18. Regarding claims 23-27, 34-38, 47-49 and 51-53, Badilini discloses identifying and measuring three RR intervals from at least three heartbeats (par. 0046, col. 2).

19. Regarding claims 29, 30, 40, 41, 50 and 54, Badilini discloses saving the file in a bitmap format which can include the annotations and measured intervals, so that the ECG may be analyzed by medical personnel with less error (par. 0002, 0014 and 0060).

#### ***Allowable Subject Matter***

20. Claims 6-8, 10, 16-18, 45 and 46 are allowed.

21. Claims 43 and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-

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4949. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every other Friday between 9AM and 5PM. A voice mail or E-mail message ([carl.layno@uspto.gov](mailto:carl.layno@uspto.gov)) may be left if desired.

All faxed communications should be sent to the Office's Official FAX number (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Toni Hakim whose telephone number is (571) 272-4353.

/Carl H. Layno/  
Supervisory Patent Examiner, Art Unit 3766